DETAILED ACTION

This Office Action is in response to Applicant's amendment filed September 26, 2009. Claims 1, 4-5, 8-20, and 22-29 are pending in the application. Claims 1, 4, 11, and 17 have been amended. Claims 15-17and 29 were withdrawn from consideration as being drawn to a nonelected species in the previous office action. Claims 1, 4-5, 8-14, 18-20, and 22-28 will presently be examined to the extent they read on the elected subject matter of record.

Upon further review and search update, information disclosed in Applicant's specification and improper interpretation of claim dependency necessitates new ground(s) of rejection. Previous indication of allowability (see the Office action of July 7, 2009, page 5) is hereby withdrawn.

Status of the Claims

The rejection of claims 1 and 11-14 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-20 and 40 of U.S. Patent No. 6,340,475 **is maintained**.

Double Patenting

Claims 1 and 11-14 of this application conflict with claims 19-20 and 40 of U.S. Patent Application Publication No. 2001/0018070, now US Patent No. 6,340,475. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the

conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 11-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-20 and 40 of U.S. Patent No. 6,340,475. Although the conflicting claims are not identical, because they are not patentably distinct from each other because both applications are directed towards a method of delivering a pharmacologically active agent by orally administering to a patient in the fed mode a therapeutically effective amount of the active agent and at least one biocompatible, hydrophilic polymer that swells upon absorption of water from gastric fluid in order to promote gastric retention. In the instant claims, the dosage form is a matrix/active agent tablet, wherein the active is ciprofloxacin. Claim 19 in U.S. Patent No. 6,340,475 does not provide for a matrix/active agent tablet dosage, however, it would have been obvious to one skilled in the art that the drug would have been dispersed in a polymeric matrix that is water-swellable rather than merely hydrophilic and that has an erosion rate that is substantially slower than its swelling rate, and that releases the drug primarily by diffusion, as taught in the specification. Therefore, the scopes of the copending claims overlap and thus they are obvious variants of one another.

Response to Arguments

Applicant's arguments filed September 26, 2009 have been fully considered but they are not persuasive. Applicant argues that by amending independent claim 1 to add

the limitations of claim 3, "wherein following said administration to a patient in the fed mode, the dosage form is retained in the upper gastrointestinal tract for a time period of about 4 to 9 hour". In response to Applicant's arguments, the amendment to the claims continues to be an obvious variant of the claims in U.S. Patent No. 6,340,475. Section (d) of claim 19 recites "releases substantially all of said drug within about 10 hours after such immersion". The recitation of about 10 hours, reads on the about 4 to 9 hours of retention in the instant application. The claims remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "treating a human patient suffering from a bacterial infection", does not reasonably provide enablement for "preventing or curing a human patient suffering from a bacterial infection". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims 18-20 are drawn to a method of treating a human patient suffering from a bacterial infection that is responsive to the oral administration of ciprofloxacin, comprising orally administering to the subject in a fed mode a therapeutically effective amount of the dosage form of claim 1. Because applicants' elected to provide "special definitions" for the terms, "treatment" or "treat," which

includes prevention of the occurrence of symptoms and/or their underlying cause. Thus, for example, "treating" a patient involves prevention of a particular disorder or adverse physiological event in a susceptible individual.... (see page 9, paragraph 29).

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention.

Attention is directed to *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman,* 230 USPQ 546 (BdAPIs 1986) at 547 the court recited eight factors:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention: The instant invention pertains to a method of treating a human patient suffering from a bacterial infection that is responsive to the oral administration of ciprofloxacin, comprising orally administering to the subject in a fed mode a therapeutically effective amount of the dosage form of claim 1.

State of the art: The skilled artisan would view that preventing the occurrence of

symptoms and/or their underlying cause or prevention of a particular disorder in a susceptible individual with a dosage form as defined in claim 1 is highly unlikely. Ciprofloxacin is the active ingredient in the dosage formulation. It is the active agent that is used to treat the disorder. Ciprofloxacin is used to treat lower respiratory tract infections, pneumonia, infections of the kidneys, sepsis, and inhalation anthrax. Ciprofloxacin is used to prostatitis, an infection of the prostate. There are three types of prostatitis, acute bacterial, chronic bacterial, and chronic nonbacterial prostatitis/chronic pelvic pain syndrome (Prostatitis Information Sheet, page 1). Prostatitis is caused by several conditions and medical procedure such as recently having had a medical instrument, such as a urinary catheter, inserted during a medical procedure or an enlarged prostate (Prostatitis Information Sheet, page 2). Prostatitis has several treatment options, including antibiotic medicine, but these are not effective treatments for noninfectious prostatitis. Prostatitis is a treatable disease. Even if the problem cannot be cured, relief from symptoms by following the recommended treatment is possible (Prostatitis Information Sheet, page 3). This statement indicates there is no prevention of prostatitis.

Relative skill of those in the art: The relative skill of those in the art is high, typically requiring an advanced professional degree.

The level of predictability in the art: The prevention of the occurrence of symptoms and/or their underlying cause or prevention of a particular disorder in a susceptible individual with a dosage form as defined in claim 1 with ciprofloxacin as the active agent is highly unpredictable. For example, to date there are no cures or

preventions for prostatitis, especially when the causes include enlarged prostate. There are no preventative measures for enlarged prostates, nor can one predict who is susceptible to an enlarged prostate that can lead to prostatitis.

The amount of direction provided by the inventor: The specification discloses in example 4, page 52 that pharmacokinetics of two formulations of gastric retentive tablets of ciprofloxacin hydrochloride and the immediate release tablet were compared in 15 healthy volunteers. The specification does not disclose data pertaining to the prevention of the occurrence of symptoms or prevention of a particular disorder.

Existence of working examples: The specification fails to provide scientific data and working embodiments with respect to "prevention of the occurrence of symptoms or prevention of a particular disorder".

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure: One of ordinary skill in the art would have to conduct a myriad number of experiments where just one set of experiments would include screening an experimentally acceptable number of patients infected who are susceptible to a particular disorder that can be treated with the dosage formulation as recited in claim 1. This experimentation could take years, as there any number of individuals that are susceptible to "a particular disorder". As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation.

Therefore, in view of the *Wands* factors, e.g., the state of the prior art, limited working examples, and the predictability of the art discussed above, to practice the

claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to test the method in the instant claim as to whether prevention of damage by pests would be likely with an assurance of success.

Applicant can overcome the scope of enablement rejection by deleting the term "prevention" from the specification.

Allowable Subject Matter

Claims 4-5, 8-10, and 22-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims are free of the prior art. The closest prior art, Shell et al. (U.S. 5,972,389), teaches administering a plurality of particles, which are specifically designed to rapidly fall apart upon administration. Shell et al. teaches when the dosage is in the form of a tablet or capsule, the form would rapidly dissolve or disintegrate upon contact with the gastric fluid to permit the particles to quickly disperse in the stomach. Shell et al. does not suggest or teach a method of administering a dosage form that maintains its size for an extended period of time before it is diminished by erosion.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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